

## EU Declaration of Conformity

**Manufacturer Name:** Suzhou Yuyue Medical Technology Co., Ltd.

**Manufacturer address:** No.9 Jinfeng Road, Suzhou Science & Technology Town, 215163 Suzhou, Jiangsu, PEOPLE'S REPUBLIC OF CHINA

**SRN:** CN-MF-000015854

**EC-Representative name:** Metrax GmbH

**Address:** Rheinwaldstr.22, 78628 Rottweil, Germany

**SRN:** DE-AR-000005481

**Tel:** +49-741-257-0, +49-741-257-223

**Fax:** +49-741-257-21

**Product name:** Sleep apnea breathing therapy mask

**Trade name:** Nasal Mask

**Intended Purpose:**

The mask is a noninvasive accessory used for channeling airflow (With or without supplemental oxygen) to a patient from a positive airway pressure (PAP) device such as a continuous positive airway pressure (CPAP) or bi-level system.

- The mask is to be used by adult patients (weighing>30kg), intended for single-patient reuse in the home environment.
- The mask is intended for single-patient use in the hospital or institutional environment..

**Models:** YN-01 / YN-02 / YN-03 / YN-03T / YN-05 / YN-06

**Basic UDI-DI:** 69221665YNM001QC

**EMDN code:** R03010102

**CS applied:** N/A

**Classification:** Class IIa, Rule 2, according to the Annex VIII of MDR.

**Conformity Assessment Route:** MDR Annex IX, Chapter I & III

**We herewith declare that:**

Our sole responsibility to the compliance of the above medical device with the applicable medical devices regulation (EU) 2017/745 of the European Parliament and of the council of 5 April 2017 on medical devices. All the supporting documents and files are retained under the premises of the manufactures.

Suzhou Yuyue Medical Technology Co., Ltd. is exclusively responsible for this declaration of conformity.

**Notified Body Name:** TUV SUD Product Service GmbH

**Address:** Ridlerstrasse, 6580339, Munchen, Germany

**Code:** 0123

**CE Certificate No.:** G10 092486 0011 Rev.01

**Valid until:** 2028-09-13

**Name:** Wang Yubin

**Signature:**

Wang Yu Bin

**Function:** General Manager

**Place:** Suzhou, Jiangsu, P.R.CHINA

**Date:**

2025.2.7